

## **Protocol for Feasibility Study of Project Carer Matters**

**Date Protocol Created:** 1 May 2021

### **The Study**

#### **Aims**

We will conduct a mixed-methods study to (1) Evaluate the feasibility of SHARE for caregivers of PwD and to (2) Explore perspectives of key stakeholders who are directly or indirectly involved with SHARE, to better understand the potential sustainability of this framework.

The objectives of our study are as follows:

1. To explore the perceptions, attitudes and beliefs of family caregivers, healthcare workers and community partners towards SHARE.
2. To explore the barriers and facilitators of acceptance and implementation of SHARE.
3. To gain insights into the perceived demand of SHARE.
4. To gain insights into the family caregivers' preliminary responses to and outcomes from SHARE.

#### **Design**

A convergent parallel mixed-methods study design will be used to collect, analyse, and interpret quantitative and qualitative descriptive data (Creswell & Creswell 2018).

Our overall evaluation of the SHARE programme is built off the Theory of Change (ToC) conceptual framework. This is a pragmatic framework which is focused on mapping out how and why a programme is expected to work and achieve its desired goals in the real world as opposed to in a research setting, and has been used widely around the world (De Silva et al., 2014; Esponda et al., 2021). It does this by first identifying the desired impact and long-term outcomes, then looks backwards to identify all the preconditions (i.e. short- and medium-term outcomes) that must be in place for the long-term outcomes to be achieved. The interventions needed to move from one precondition to the next for achieving the long-term outcomes are also identified. This approach allows us to better clarify the aims, objectives and outcomes of SHARE and the mechanisms that underpins the programme's ability to affect the caregiving ecosystem (De Silva et al., 2014).

Our initial ToC map is presented in Figure 2. This map describes the causal pathways of how SHARE achieves the long-term outcome in caregivers of "improved capacity for sustained caregiving of the PwD". This was built off a discussion with a range of stakeholders - hospital leaders, community partners, care support nurses, and ward nurses – which led to a consensus on the process and outcome indicators for each precondition in the pathway, and the key assumptions which set out the conditions which the casual pathway needs to achieve the impact.

#### **Study setting**

Our study will involve six inpatient wards of a 1,700-bedded tertiary care hospital which are piloting SHARE. These wards comprise of four acute wards and two sub-acute wards. They are selected as

they admit a comparatively greater number of patients with dementia than other wards in the hospital. The study will be conducted over 12 months.

## **Participants**

### Quantitative data collection

Our quantitative data is based off programme data collected from all caregivers who undergo SHARE. Hence, it will consist of all caregivers of PwD whose care recipient is admitted into the pilot wards and agree to participate in SHARE.

### Qualitative data collection

We will be collecting data from key stakeholders of the different components of the SHARE programme. The key stakeholders comprises: (1) Family caregivers of PwD (n = 25 to 30), (2) Ward nurses (n= 8 to 10), (3) Care support nurses (n = 2 to 3), (4) Intervention programmes facilitators and standardized patients (n = 3), (5) Community partners and hospital leaders (n = 4), and (6) Other clinicians - medical social workers, physiotherapists, occupational therapists and doctors (n = 4 to 5).

### Eligibility criteria

#### Qualitative data collection

Our inclusion criteria for participants in our qualitative data collection is as follows:

For family caregivers, we would recruit individuals who are (1) Above 21 years of age, (2) The main family caregiver of the PwD receiving home-based care, (3) Able to converse in English language, and (4) Willing to have their interviews audio-recorded.

For ward nurses, we would recruit individuals who are (1) Above 21 years of age, (2) Working as a nurse at one of the inpatient wards piloting SHARE, (3) Referred family caregivers to complete the brief screening tool, and (4) Willing to have their interviews audio-recorded.

For care support nurses, other clinicians, and programme facilitators, we would recruit individuals who are (1) Above 21 years of age, (2) Involved in either providing direct or indirect patient care to a PwD and their caregiver through SHARE, and (3) Willing to have their interviews audio-recorded.

For hospital management and leaders, we would recruit individuals who are (1) Above 21 years of age, (2) Key decision makers or in leadership positions within the hospital, and (3) Willing to have their interviews audio-recorded.

For representatives of social service agencies, we would recruit individuals who are (1) Above 21 years of age, (2) Working in institutions where there are ongoing or potentially future partnerships with TTSH to provide care services for PwD and their caregivers, (3) Key decision makers or in leadership positions within their institutions and (4) Willing to have their interviews audio-recorded.

We will exclude any potential participant who refuses to have their interviews recorded.

### Quantitative data collection

Our eligibility criteria for participants to enter SHARE - whose information is captured in our quantitative data collection – are as follows: Family caregivers of a PwD who are (1) Above 21 years of age, (2) The main family caregiver of the PwD receiving home-based care, and (3) Able to read and converse in English.

We will exclude any caregiver whose care recipient is planned for discharge to a long-term care facility, such as a nursing home.

### Recruitment

#### Qualitative data

Family caregivers of PwD admitted into the pilot wards who fit our inclusion criteria will be highlighted to the study team by attending clinical staff in the ward. The study team will approach these caregivers to further explain the study details and assess their eligibility for participation. Individuals who agree to participate will be met by the study team to provide written consent.

Ward nurses and other clinicians who are eligible will receive a recruitment letter distributed by their department heads. The study team will also join their department meetings and roll calls to share the study. The study team will approach individuals who express interest to further explain the study details and assess their eligibility for participation. Individuals who agree to participate will be met by the study team to provide written consent.

Hospital management staff and representatives of social service agencies will receive a letter of invitation via email, with the study team contact details attached within for reference. This would allow interested individuals to directly contact the study team. The team will then further explain the study details and assess their eligibility for participation. Individuals who agree to participate will be met by the study team to provide written consent.

#### Quantitative data

Family caregivers of PwD who are eligible for SHARE will be invited by ward staff to perform the brief needs assessment and hence receive the appropriate SHARE interventions. Verbal consent is obtained before they receive the interventions, that their information will be used to help evaluate the programme.

### **Data Collection**

Our strategy for data collection and analysis is built off the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework. This would allow us to examine if the essential SHARE elements, (1) Affects our target population of caregivers of PwD – *Reach*, (2) brings about the desired effects in caregiver participants – *Effectiveness*, (3) are taken up well by our target population, healthcare and community service providers - *Adoption*, (4) are adhered according to our proposed implementation plan - *Implementation* and (5) are suitable for scaling and sustainment without excessive modification from the originally-planned framework of SHARE – *Maintenance* (Gaglio, Shoup, & Glasgow, 2013; Glasgow, Vogt, & Boles, 1999). Through the RE-AIM framework we can obtain the findings needed to improve the sustainable take-up and delivery of SHARE effectively and holistically. This approach has also shown promise in the evaluation of community-based

support programmes for caregivers (Samia, Aboueissa, Halloran, & Hepburn, 2014; Stevens, Smith, Trickett, & McGhee, 2012).

Data collection will primarily consist of qualitative interviews, with some quantitative methods as detailed below.

## **Procedures**

### Qualitative data collection

We will conduct one-time individual interviews using semi-structured interview guides with key stakeholders of the SHARE programme. The interviews will focus on (1) their views of SHARE, (2) facilitators and barriers to acceptability and implementation of SHARE, (3) issues associated with sustaining SHARE, and (4) processes that need to be fine-tuned for the scaling and sustaining of SHARE.

All interviews will be audio-recorded and conducted on a voluntary basis. One researcher who is well-trained in qualitative research methods and independent of the development and execution of SHARE will conduct all the interviews. In addition, emotions, pauses, non-verbal language, and significant observations of the participants which could not be captured by audio recording will be recorded as field notes.

### Quantitative data collection

We will also be collecting indicators related to the demand and acceptability of the SHARE programme. The following data will be collected: (1) SHARE programme log to store information related to the demand for the SHARE such as number of family caregivers screened, number of family caregivers assessed for needs, number of family caregivers provided with assistance through in-house services or referred to our partnered community-based agencies, etc. The log will also document information related to the work or implementation processes such as length of time to perform the screening and needs assessment, training hours for ward nurses and CARER facilitators, and etc; (2) SHARE programme satisfaction survey to ask family caregivers about their satisfaction with the SHARE programme; (3) Intervention programme log to store information related to the demand for the caregiver intervention programme such as the demographics of participants for each intervention programme, attendance and drop-out rate of the programme, and etc; (4) Intervention programme surveys that capture appropriate psychological measures such as caregiver burden as measured using a modified version of the Zarit Burden Inventory, caregiver anxiety and depression as measured using the Hospital Anxiety and Depression scale, caregiver competence as measured using the Caregiver Competence scale and caregiver mastery as measured using the Personal Mastery scale (Pearlin, Mullan, Semple, & Skaff, 1990; Pearlin & Schooler, 1978; Zarit, Reever, & Bach-Peterson, 1980; Zigmond & Snaith, 1983); (5) Intervention programme satisfaction surveys; and (6) Dementia forum satisfaction surveys.

## **Data analysis**

### Qualitative analysis

Audiotape recordings for each interview will be transcribed verbatim and double-checked to ensure the accuracy of transcription. Transcripts will be sorted, coded, and categorized accordingly to facilitate thematic analysis, aligning codes, subthemes and themes against the Reach, Effectiveness, Adoption, Implementation and Maintenance of SHARE. Our application of the ToC model would help ensure completeness of our inquiry and understanding of the relevant factors that enable or hinder the effective rollout and engagement of SHARE by caregivers and other stakeholders in the hospital and community ecosystem (Holtrop, Rabin, & Glasgow, 2018).

#### Quantitative analysis

Descriptive statistics such as mean, standard deviation, median and interquartile range will be used to describe caregiver-specific outcomes captured. Paired-t-tests will be applied to examine the effect of SHARE interventions on caregivers' reported depression, anxiety, and mastery scores before and after SHARE interventions. Data analysis will be conducted using IBM SPSS version 25 (IBM Corp, 2016). Statistical significance will be set as  $p < 0.05$ .

#### Data triangulation

Both qualitative and quantitative data will be triangulated using the RE-AIM framework address the research objectives of our study. These insights will then be used to generate an updated ToC model explaining how SHARE improves caregiver capacity for sustained caregiving of the PwD. This final ToC model will reflect the processes and mechanisms of SHARE that contribute towards the short, medium and long-term outcomes we intended, and can serve as a guide for future researchers and practitioners.

#### **Ethical Considerations**

The purpose of this study will be explained to prospective eligible study participants, and the expected level of involvement. Potential caregiver participants will be reminded by the research assistant that their participation in the study is voluntary, and that it would not affect their ability to engage in the interventions within the SHARE Programme.

Written consent will be sought from individuals who agree to participate in the semi-structured interviews. Each participant will retain a signed copy of the consent form containing the Principal Investigator's contact details if they have further queries. A token cash voucher will be provided to participants after their completion of the interview as reimbursement for their participation in the study.

As the quantitative data collected in this study consists of the programme logs and data of all SHARE participants, verbal consent is sought from all caregivers identified to receive SHARE interventions, with a participant information sheet that as part of the evaluation and improvement of the service, the information they furnish will be anonymized and aggregated for analysis.

#### Ethical review

The study protocol was reviewed and approved by the National Healthcare Group Domain Specific Review Board (DSRB Ref: 2020/00087). This study has also been externally peer-reviewed and awarded funding through the Geriatric Education and Research Institute (GERI) Intramural Project

Grant (GERI Ref: GERI1626) on 15 May 2020 for this study, with approval for its conduct from 01 Dec 20 to 31 Mar 2022.

### **Validity and Rigour**

To ensure rigour in our study, we will apply the principles specific to both the qualitative and quantitative study designs.

#### Qualitative validity

The credibility of our qualitative analysis will be ensured by complying with the recommended principles for qualitative analysis when applying the RE-AIM framework (Gaglio et al., 2013; Holtrop et al., 2018; Ward, Furber, Tierney, & Swallow, 2013). Two researchers will code all transcripts independently, ensuring consistency in the coded data across the multiple groups of participants.

#### Quantitative validity

The outcome measures used in this study – the Caregiver Competency Scale, the Caregiver Mastery Scale, the Hospital Anxiety and Depression Scale and the Zarit Burden Interview, have been validated for use in local caregivers of PwD in our earlier research (Chan et al., 2018; Chan, Lim, et al., 2019). In addition, these measures have been shown to be both easy to understand and capable of being self-administered by caregivers, making them appropriate tools for use.

## Figures

Figure 1: Framework of SHARE Programme

Figure 2: Proposed Theory of Change map for SHARE Programme

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